

# SPECIFICATION

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## ***BALLOON CONFIGURING APPARATUS***

### **Background of Invention**

- [0001] Medical balloons are used in the body in a variety of applications including as dilatation devices for compressing plaque and for expanding prosthetic devices such as stents at a desired location in a bodily vessel. Because it is typically necessary for the balloon to traverse a tortuous anatomy as it is being delivered to the desired location in the bodily vessel, it is desirable for the balloon to assume as low a profile as possible.
- [0002] One way to achieve a low profile is by folding the balloon to form a number of wings. In accordance with the prior art, wings may be formed in a partially inflated balloon by imparting an inward radial force about the periphery of the balloon using a plurality of rigid blades which are distributed about the periphery of the balloon. As the blades move radially inward, wings are formed in the balloon.
- [0003] When forming wings in balloons in this manner, however, special care must be taken to ensure that the blades do not have any sharp edges or burrs which would damage the balloon. Also, caution must be exercised to prevent the blades from applying damaging forces to the balloon and/or any structures underlying the balloon such as markerbands, bonds or hubs. Although the amount of force applied to the balloon may be reduced to avoid damaging the balloon and/or any underlying structures, sufficient force must, nevertheless, be applied to completely form the balloon wings so as to achieve the desired cross-section. As such, a great deal of precision is needed in determining the closed position of the blades. The problem is exacerbated when a single device is to be used to fold balloons on catheters of different cross-sections.
- [0004] There remains a need for innovative devices for forming balloon folds and for innovative devices which may be used to form balloon folds on catheters of different cross-sections.

[0005] All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

[0006] Without limiting the scope of the invention in any way, the invention is briefly summarized in some of its aspects below. Additional details of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

[0007] A brief abstract of certain aspects of the technical disclosure in the specification is provided as well for the purposes of complying with 37 C.F.R. 1.72.

## Summary of Invention

[0008] In one embodiment, the invention is directed to a device for configuring an inflatable balloon of a balloon catheter assembly. The device comprises a body which comprises a plurality of inflatable members defining a channel therebetween. The channel is sized to accommodate at least a portion of a balloon catheter. Each inflatable member has a balloon contacting portion. Upon inflation of the inflatable members, the balloon contacting portions apply an inward force to a balloon catheter disposed in the channel. Desirably, the inflatable members are disposed about the circumference of a circle. Typically, the device comprises three to twelve inflatable members. The inflatable members may take on any configuration to provide an appropriate balloon contacting portion. Some non-limiting examples of suitable configurations include generally tubular inflatable members having circular cross-sections and generally tubular inflatable members having wedge-shaped cross-sections.

[0009] The inflatable members may be disposed in numerous configurations about the channel. In one configuration, the plurality of inflatable members may include at least two inflatable members which are disposed end-to-end along the length of the channel. In another configuration, the inflatable members may be disposed in one or more spirals about the channel where it is desired to provide spiral folds in a balloon. In yet another configuration, the inflatable members may include at least two inflatable members which are circumferentially and axially displaced from one another. Desirably, inflatable members which are circumferentially and axially displaced from one another are shorter in length than the balloon.

[0010] The device may further comprise a housing comprising one or more housing

members in which the inflatable members are disposed. The housing constrains the inflatable members and allows the inflatable members to apply the necessary force to the balloon. Typically, the housing will be in the form of a rigid tube with optional first and second end caps. Desirably, the first end cap is disposed at the first end of the rigid tube across a first opening of the rigid tube and the second end cap disposed at the second end of the tube across a second opening and the inflatable members contact the first and second end caps. In some embodiments, the first and second end caps can support the inflatable members and serve to align the inflatable members. Typically, at least one of the end caps will have an opening therethrough sized to receive at least a portion of a balloon catheter therethrough.

[0011] The invention is also directed to a device for configuring an inflatable balloon of a balloon catheter assembly, where the device includes a body comprising an inflatable member having a balloon contacting portion and a catheter support member constructed and arranged relative to the body to support a catheter in a region adjacent the balloon contacting portion of the inflatable member.

[0012] The inflatable member optionally comprises a plurality of balloon contacting portions. The balloon contacting portions are desirably spaced about the circumference of a circle and the catheter support member is constructed and arranged to support a catheter in a region between the balloon contacting portions.

[0013] The device may further comprise one or more constraining members which constrain the inflatable member and allow the inflatable member to apply the necessary force to the balloon. Optionally, the constraining members may be in the form of a plurality of slats each of which is disposed between adjacent balloon contacting portions.

[0014] Typically, a housing will be provided. A suitable housing in the form of a rigid tube having a first end with a first opening and a second end with a second opening and a passage therethrough may be used.

[0015] In another embodiment, the device may comprise a plurality of inflatable members each of which has a balloon contacting portion. The inflatable members are disposed about the circumference of a circle and the catheter support member is constructed and arranged to support a catheter in a region between the balloon contacting portions.

[0016] The invention is also directed to method of configuring a medical balloon. In